APR 15 2005

510(k) Summary

SUBMITTER:	In-X Corporation 6753 E. 47th Ave. Drive, Unit D Denver, CO 80216
CONTACT PERSON:	Douglas Powell, In-X Corporation President Phone: 303-574-3115 ext 103 Fax: 303-574-3114
DATE PREPARED:	October 22, 2004
DEVICE TRADE NAME:	Home-Away System, Model 1041
510(K) NUMBER	K042944
PRODUCT CODES	CAW/BYJ
REGULATION NUMBER	868.5440/868.5655
REGULATORY CLASS	Class II (two)
COMMON/USUAL NAME:	Accessory to oxygen concentrator and liquid oxygen stroller
CLASSIFICATION NAME:	Portable Oxygen Generator Portable Liquid Oxygen Unit
PREDICATE DEVICE:	The Home-Away System 510(k) Number: K004047

DEVICE DESCRIPTION:

The Home-Away System, Model 1041 is an accessory to an oxygen concentrator and liquid oxygen (LOX) stroller. It liquefies oxygen that is received from an oxygen concentrator, stores it, and delivers it to a LOX stroller for patient use. While performing these functions, it is also capable of delivering up to 3 L/min of gaseous oxygen directly to the patient. In these respects, the Home-Away System, Model 1041 is the same as its predicate, the Home-Away System. The Home-Away System, Model 1041 incorporates changes from the cleared device that enhance its usability, manufacturability, consistent performance, durability, reliability, and safety.

INDICATIONS FOR USE:

The Home-Away System, Model 1041 is intended as an accessory to an oxygen concentrator and liquid oxygen storage system for use as an aid or adjunct to delivering

supplemental oxygen therapy in the home. It is intended to be used with both pediatric and adult patients. It is not intended to be a life-sustaining or life-supporting device. The device has no contraindications.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

The Home-Away System, Model 1041 is substantially equivalent to the cleared Home-Away System (K004047). They are both compatible with oxygen concentrators that deliver $\geq$ 5 L/min USP 93% oxygen and are approved by In-X Corporation. The Home-Away System is compatible with any bottom-fill type LOX stroller; whereas, the Home-Away System, Model 1041 is only compatible with LOX strollers that utilize a proprietary mating valve.

Substantial equivalence was based on performance testing of the Home-Away System, Model 1041 consisting of analysis of oxygen for impurities, USP 93% oxygen testing, EMC/EMI testing, safety testing, transfill testing, production rate testing, shock and vibration testing, package testing, environmental testing, and residue testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Mr. Douglas Powell
President
In-X Corporation
6753 East 47th Avenue, Unit D
Denver, Colorado 80216

Re: K042944
Trade/Device Name: Home-Away System, Model 1041
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW, BYJ
Dated: April 11, 2005
Received: April 12, 2005

Dear Mr. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042944

Device Name: Home-Away System, Model 1041

Indications for Use: The Home-Away System, Model 1041 is intended as an accessory to an oxygen concentrator and liquid oxygen storage system for use as an aid or adjunct to delivering supplemental oxygen therapy in the home. It is intended to be used with both pediatric and adult patients. It is not intended to be a life-sustaining or life-supporting device. The device has no contraindications.

Prescription Use__X___ (21 CFR 801 Subpart D) **AND/OR** **Over-the-Counter Use_____** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number) K042944